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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,987	04/20/2001	Ronald S. Chamberlain	2026-4231US3	2855

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EXAMINER

WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/838,987

Applicant(s)

CHAMBERLAIN ET AL.

Examiner

Michael C. Wilson

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): see attached.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: it does not address the pending 103 rejections.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 1-8, 21 and 22

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____


MICHAEL WILSON
PRIMARY EXAMINER

DETAILED ACTION

The amendment filed 12-13-04 states clarifies that claims 9-20 have been canceled. The amendment also cancels claim 23. Claims 1-8 and 21 and 22 are pending in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

In claim 5, the language remains wordy and confusing. Delete "encoding said antigen" for clarity. (It is readily apparent that the "nucleic acid inserts of the first and second recombinant vectors" refers to both the insert in the "first recombinant vector" of a) and in the "second recombinant vector" of b). The word "comprises" should be "comprise." The phrase "other than said antigen" should be --that is not said antigen-- or --, wherein said immunostimulatory protein is not said antigen-- to clearly indicate the immunostimulatory protein is not the antigen.

Claim Rejections - 35 USC ' 112

The rejection of claim 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn because the claim has been canceled.

The rejection regarding claim 23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

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which applicant regards as the invention has been withdrawn because the claim has been canceled.

Claim 5 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record, i.e. the phrase "said antigen against which an immune response is to be induced" in claim 5 lacks antecedent basis.

Claim Rejections - 35 USC ' 103

The rejection of claim 23 under 35 U.S.C. 103(a) as being unpatentable over Wang (May 1, 1995, J. Immunol., Vol. 154 (9) 4685-92) has been withdrawn because the claim has been canceled.

The rejection of claim 23 under 35 U.S.C. 103(a) as being unpatentable over Wang (May 1, 1995, J. Immunol., Vol. 154 (9) 4685-92) has been withdrawn because claim 23 has been canceled.

The rejection of claim 23 under 35 U.S.C. 103(a) as being unpatentable over Wang (J. Immunol., (1995 May 1) 154 (9) 4685-92) in view of Zhai (Jan. 15, 1996, J. Immunol., Vol. 156, No. 2, pages 700-710) has been withdrawn because claim 23 has been canceled.

Claims 1-3 and 5-7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (May 1, 1995, J. Immunol., Vol. 154 (9) 4685-92) for reasons of record.

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Wang taught administering a wild-type vaccinia virus (VV) to mice followed by administering a fowlpox virus (FPV) encoding β -gal which caused an increase in CTL response in splenocytes as compared to administering wild-type vaccinia followed by vaccinia encoding β -gal (pg 4689, col. 2, Fig. 6, 1st full ¶). The increased CTL response is "an immune response" against the "at least one antigen" as claimed. Wang did not teach administering VV- β -gal followed by administering FPV- β -gal. However, Wang taught a vaccinia VV- β -gal. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer VV- β -gal followed by FPV- β -gal as taught by Wang. One of ordinary skill in the art at the time the invention was made would have been motivated to replace wild-type VV with VV- β -gal to introduce the DNA encoding β -gal sooner thereby inducing the immune response sooner.

Similarly, Wang taught administering a wild-type FPV followed by VV- β -gal, which also caused an immune response (page 4689, col. 2, 1st ¶). Wang did not teach administering FPV- β -gal followed by VV- β -gal. However, Wang taught administering FPV- β -gal caused an immune response. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer FPV- β -gal followed by VV- β -gal. One of ordinary skill in the art at the time the invention was made to replace wild-type FPV with FPV- β -gal to introduce the DNA encoding β -gal sooner and induce the immune response sooner. Claim 5 is included because VV and FPV encode viral proteins that are recognized as foreign and induce an immune response.

Applicants have not addressed the rejection.

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Claims 1-3, 5-7, 21 and 22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (May 1, 1995, J. Immunol., Vol. 154 (9) 4685-92) for reasons of record.

Wang taught administering VV- β -gal to mice followed by FPV- β -gal or vice versa, which caused an immune response (see 103 rejection above). Wang did not expressly teach replacing β -gal with MART-1 or gp100. However, Wang suggested replacing β -gal with MART-1 and gp100 and taught making FPV-MART-1 and FPV-gp100 (pg 4690, col. 2, last 2 ¶). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Wang wherein the β -gal gene is replaced with MART-1 or gp100 as suggested by Wang. One of ordinary skill in the art at the time the invention was made would have been motivated to replace β -gal with MART-1 or gp100 to determine if self proteins such as MART-1 or gp100 induced the same immune response as β -gal and to determine if MART-1 or gp100 enhanced the precursor frequency of T-cells that recognize MART-1 or gp100 prior to ex vivo expansion (pg 4690, col. 2, ¶ 2, line 4).

Applicants have not addressed this rejection.

Claim 1-8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (J. Immunol., (1995 May 1) 154 (9) 4685-92) in view of Zhai (Jan. 15, 1996, J. Immunol., Vol. 156, No. 2, pages 700-710) for reasons of record.

Wang taught administering VV- β -gal to mice followed by FPV- β -gal, which caused an increase in CTL response in splenocytes as compared to administering two

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doses of vaccinia virus encoding β -gal. Wang did not teach replacing the vaccinia virus or fowlpox virus with an adenovirus. However, Zhai taught administering an adenoviral vector encoding β -gal to mice and obtaining an immune response.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Wang wherein the vaccinia virus or fowlpox virus was replaced with the adenoviral vector taught by Zhai. One of ordinary skill in the art at the time the invention was made would have been motivated to replace the vaccinia virus (the first vector) with the adenoviral vector to increase the CTL response against antigen as compared to administering adenoviral vector followed by readministration of adenoviral vector. One of ordinary skill in the art at the time the invention was made would have been motivated to replace the fowlpox virus (the second vector) with the adenoviral vector to determine if fowlpox was the only virus that could be used to obtain a CTL response against antigen after administering vaccinia virus.

Applicants have not addressed this rejection.

Conclusion

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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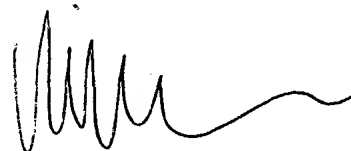
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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 571-272-0804.

The official fax number for this Group is (703) 872-9306.

Michael C. Wilson



MICHAEL WILSON
PRIMARY EXAMINER